

HERSTELLBERICHT FÜR ENTWICKLUNGSCHARGEN

- - Augengele - -

| | | | | |
|--|-------------------------|-----------------------------|------------------------------------|-----------|
| Präparat: <i>Dexamethason - Gel</i> | Ch-Bez.: <i>6166</i> | Ansatzgröße <i>500 g</i> | Herstelldatum <i>[redacted]</i> | TEIL I |
|--|-------------------------|-----------------------------|------------------------------------|-----------|

Bemerkungen (z.B. Grund der Herstellung):

Hersteller: *78*
Prüfer (Teil 1): *78*

| Lfd.Nr. | WE-Nr. | Bezeichnung | Einwaage (g) | Gehalt nach Analyse (mg/g) | der Deklaration (%) |
|---------|--------------------------|------------------------------------|-----------------|-------------------------------|------------------------|
| 1 | <i>607 1021 5612</i> | <i>Carbopol 980</i> | <i>1.5</i> | | |
| 2 | <i>1130227</i> | <i>Dexamethason-NA-phosphat</i> | <i>0.4925</i> | | <i>96.17</i> |
| 3 | <i>1190210</i> | <i>Gelirmit</i> | <i>0.05</i> | | <i>95.90</i> |
| 4 | <i>1020230</i> | <i>Gelirmit, Triplexin</i> | <i>0.05</i> | | |
| 5 | <i>0870086</i> | <i>Sorbitol</i> | <i>24.50</i> | | |
| 6 | <i>0330039</i> | <i>NaOH, fest</i> | <i>0.60</i> | | |
| 7 | <i>1</i> | <i>Wasser für Injektionszwecke</i> | <i>472.8075</i> | | |
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HERSTELLUNG:

BESONDERHEITEN BEI DER HERSTELLUNG: *Zur Einwaage von Dexamethason-NA-phosphat wurde der Wassergehalt von + 6.5% nicht berücksichtigt.*

Stabilitätsprüfung von : Dexamann visc.
Chargennummer

Präp.Nr. 190

10

Chargengröße : 500 g
Behälter : 5 g-Polyfoil-Kanülentube, Innenbeschichtung: HDPE
Herstellungsort : Dr. Mann Pharma, Berlin
Hersteldatum
Erstuntersuchung
Einlagerungsdatum
Prüfdatum : Monate

Formulation A
pH 6.3 - 7.3

05/94 : 3
09/94 : 7
02/95 : 12
08/95 : 18

| Prüfung auf | Spezifikation | Lagerzeit in Mon. | Lagerungsbedingungen | | | |
|---|-------------------------------|-------------------------|--------------------------|--------------------------------------|---------------------------------|--------------------------------|
| | | | 5°C | 21°C/45% | 26°C/60% | 31°C/70% |
| Gehalt in % Dexamethason- dihydrogen- phosphat | 90 - 105 | 0 3 7 12 18 | - 96,8 - - - | 96,2 95,7 95,8 95,1 86,3 | 96,2 94,7 91,7 86,0 | 94,5 92,5 89,2 83,9 |
| Gehalt in % Cetrinid | 90 - 105 | 0 3 7 12 18 | - - - - - | 95,9 - 101,3 98,0 100,2 | - - 101,6 97,7 99,3 | - - 99,0 97,4 99,3 |
| Dexamethason in % | max 10 % | 0 3 7 12 18 | - 0,7 - - - | n.n. 1,4 2,4 3,6 10,7 | 1,6 2,9 3,5 11,2 | 1,8 3,1 4,0 12,9 |
| Transmission in % (bei 425 nm) | > 85 % | 0 3 7 12 18 | - 95,2 - - - | 91,8 95,3 - 93,1 94,9 | 94,6 - 93,6 94,3 | 95,4 - - 93,9 |
| pH-Wert | 6,3 - 7,3 | 0 3 7 12 18 | - 7,0 - - - | 7,2 7,0 7,0 6,9 7,1 | 7,0 7,0 6,9 7,0 | 7,0 7,0 7,0 7,0 |
| Osmolalität (mosm/kg) | 285 - 335 | 0 3 7 12 | - 304 - - | 304 300 301 328 | 298 300 299 | 301 303 303 |
| Leitfähigkeit (µS/cm) | 7 - 12 | 0 3 7 | - 9,9 - | 8,7 10,1 - | 10,2 - | 10,0 - |
| Brechungsindex (n_D) | 1,339 - 1,341 | 0 3 7 | - 1,3407 - | 1,3408 1,3406 1,3407 | 1,3405 1,3406 | 1,3404 1,3406 |
| Viskosität (mPa·s) | 2000 - 3000 | 0 3 7 12 18 | - 2622 - - - | 2844 2642 2550 2911 2918 | 2652 2799 2875 2857 | 2734 2724 - |
| Aussehen | klar (DAB 10/ Ph. Eur.) | 0 3 7 12 18 | - klar - - - | klar klar klar klar klar | klar klar klar klar | klar klar klar klar |
| Farbe | 8 9 (DAB 10/ Ph. Eur.) | 0 3 7 12 18 | - 8 9 - - - | 8 9 8 9 8 9 8 9 8 9 | 8 9 8 9 8 9 8 9 | 8 9 8 9 8 9 8 9 |
| Mikrobiolog. Qualität | steril | 0 | - | steril | - | - |

n.n. = nicht nachweisbar
- = nicht untersucht

HERSTELLBERICHT FÜR ENTWICKLUNGSCHARGEN

- Augengele -

Präparat:

Dexamethason Gel

Ch.-Bez.:

[REDACTED]

Ansatzgröße

1 kg

Hersteldatum

[REDACTED]

TEIL

I

Bemerkungen (z. B. Grund der Herstellung):

Hersteller: F3

Prüfer (Teil 1): Dp/15°

Prüfdatum:

[REDACTED]

| Lfd. Nr. | WE-Nr. | Bezeichnung | Einwaage (g) | Gehalt nach Analyse mg/g | Gehalt nach Analyse der Deklaration (%) |
|----------|---------|---|--------------|--------------------------|---|
| 1 | 0860036 | Carbopol 980 | 3,00 | | |
| 2 | 0450262 | Dexamethason-21-dihydrogensulfat ^{phosphat} * | 1,102 | | 102,9 |
| 3 | 0560360 | Cetrimid | 0,100 | | 99,7% |
| 4 | 0160055 | Na-edetat | 0,100 | | |
| 5 | 0760322 | Sorbitol | 49,80 | | |
| 6 | 0760214 | NaH ₂ Po ₄ fest | 1,50 | | |
| 7 | / | dest. Wasser | | | |
| | | | | | |
| | | * H ₂ O-Gehalt der Substanz beachten = 11,05 / 945,193 | | | |
| | | | | | |

Stability test: Dexamethason Gel
 Batch number: XXXXXXXXXX
 Batch size: 1 kg
 Container: 5 g Polyfoil tubes
 Place of manufacture: Dr. Mann Pharma, Berlin
 Date of manufacture: XXXXXXXXXX
 Date of storage: XXXXXXXXXX
 Test date months

Prod. no.:

Formulation B
 pH 7.6 - 8.0

10/96 0
 02/97 3
 05/97 6
 08/97 9
 11/97 12
 05/98 18

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| Test for | Specification (release) | Months | Storage conditions | | |
|--|----------------------------|--------|--------------------|------------|------------|
| | | | 21 °C/45 % | 25 °C/60 % | 30 °C/70 % |
| Content [%] Dexamethasone sodium phosphate | 95 - 105 | 0 | 102.0 | | |
| | | 3 | 99.0 | 99.8 | 100.1 |
| | | 6 | 99.6 | 101.6 | 101.1 |
| | | 9 | 102.3 | 101.7 | 101.6 |
| | | 12 | 99.7 | 98.3 | 97.6 |
| | | 18 | 101.3 | 100.9 | 99.1 |
| Decomposition [%] Dexamethasone | n.m.t. 3 | 0 | 0.2 | | |
| | | 3 | 0.2 | 0.2 | 0.2 |
| | | 6 | 0.4 | 0.5 | 0.5 |
| | | 9 | 0.5 | 0.5 | 0.6 |
| | | 12 | 0.5 | 0.6 | 0.7 |
| | | 18 | 0.7 | 0.7 | 0.8 |
| Content [%] Cetrimide | 90 - 110 | 0 | 99.7 | | |
| | | 3 | 99.3 | 100.3 | 99.6 |
| | | 6 | 98.3 | 99.0 | 99.0 |
| | | 9 | 100.5 | 99.0 | 100.0 |
| | | 12 | 100.2 | 99.2 | 99.4 |
| | | 18 | 99.5 | 100.6 | 101.4 |
| Transmission [%] | n.l.t. 85 | 0 | 88.4 | | |
| | | 3 | 89.6 | 89.7 | 87.0 |
| | | 6 | 88.8 | 88.9 | 89.0 |
| | | 9 | 86.6 | 89.3 | 89.2 |
| | | 12 | 89.3 | 88.6 | 89.5 |
| | | 18 | 87.0 | 86.9 | 87.5 |
| pH value | 7.6 - 8.0 | 0 | 7.7 | | |
| | | 3 | 8.0 | 7.9 | 7.9 |
| | | 6 | 7.7 | 7.7 | 7.7 |
| | | 9 | 7.7 | 7.7 | 7.6 |
| | | 12 | 7.7 | 7.7 | 7.7 |
| | | 18 | 7.8 | 7.8 | 7.7 |
| Osmolality [mosmol/kg] | 280 - 320 | 0 | 305 | | |
| | | 3 | 303 | 304 | 304 |
| | | 6 | 304 | 305 | 306 |
| | | 9 | 312 | 307 | 308 |
| | | 12 | 308 | 307 | 307 |
| | | 18 | 305 | 306 | 306 |
| Viscosity [mPa·s] | 2400 - 3400 | 0 | 3075 | | |
| | | 3 | 2802 | 3451 | 3308 |
| | | 6 | 3502 | 3158 | 3403 |
| | | 9 | 2877 | 3178 | 3209 |
| | | 12 | 3022 | 3175 | 3132 |
| | | 18 | 3691 | 3804 | 3428 |

Stability test: Dexam thas n Gel
 Batch number: XXXXXXXXXX
 Batch size: 1 kg
 Container: 5 g Polyfoil tubes
 Place of manufacture: Dr. Mann Pharma, Berlin
 Date of manufacture: XXXXXXXXXX
 Date of storage: XXXXXXXXXX

Prod. no.:

4

Test date months
 10/96 0
 02/97 3
 05/97 6
 08/97 9
 11/97 12
 05/98 18

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| Test for | Specification (release) | Months | Storage conditions | | |
|--------------------------------------|--------------------------------------|--------|--------------------|------------|------------|
| | | | 21 °C/45 % | 25 °C/60 % | 30 °C/70 % |
| Colour | B 9 | 0 | B 9 | | |
| | | 3 | B 9 | B 9 | B 9 |
| | | 6 | B 9 | B 9 | B 9 |
| | | 9 | B 9 | B 9 | B 9 |
| | | 12 | B 9 | B 9 | B 9 |
| | | 18 | B 9 | B 9 | B 9 |
| Clarity and degree of opalescence | n.m.t. standard of opalescence IV | 0 | n.m.t. IV | | |
| | | 3 | n.m.t. IV | n.m.t. IV | n.m.t. IV |
| | | 6 | n.m.t. IV | n.m.t. IV | n.m.t. IV |
| | | 9 | n.m.t. IV | n.m.t. IV | n.m.t. IV |
| | | 12 | n.m.t. IV | n.m.t. IV | n.m.t. IV |
| | | 18 | n.m.t. IV | n.m.t. IV | n.m.t. IV |
| Sterility | sterile | 0 | sterile | | |